Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Clinical practice guideline: polysomnography for sleep-disordered breathing prior to tonsillectomy in children.

Bibliographic Source(s)

Roland PS, Rosenfeld RM, Brooks LJ, Friedman NR, Jones J, Kim TW, Kuhar S, Mitchell RB, Seidman MD, Sheldon SH, Jones S, Robertson P. Clinical practice guideline: Polysomnography for sleep-disordered breathing prior to tonsillectomy in children. Otolaryngol Head Neck Surg. 2011 Jul;145(1 Suppl):S1-15. PubMed

Guideline Status

This is the current release of the guideline.

A scheduled review process will occur at 5 years from publication or sooner if new compelling evidence warrants earlier consideration.

Recommendations

Major Recommendations

The evidence grades (A-D, X) and evidence-based statements (Strong Recommendation, Recommendation, and Option) are defined at the end of the "Major Recommendations" field.

Statement 1. Indications for Polysomnography (PSG)

Before performing tonsillectomy, the clinician should refer children with sleep-disordered breathing (SDB) for PSG if they exhibit any of the following: obesity, Down syndrome, craniofacial abnormalities, neuromuscular disorders, sickle cell disease, or mucopolysaccharidoses.

Recommendation based on observational studies with a preponderance of benefit over harm.

Evidence Profile

- Aggregate evidence quality: grade C, observational studies; 1 systematic review of observational studies on obesity
- Benefit: PSG confirms indications and appropriateness of surgery, helps plan perioperative management, provides a baseline for postoperative PSG, and defines severity of sleep disturbance
- Harm: none
- Cost: procedural cost; indirect cost of missed work
- Benefits-harm assessment: preponderance of benefit over harm
- Value judgments: knowledge gained through PSG can assist in diagnosing those children with significant SDB; belief that PSG can improve

surgical outcomes through improved perioperative planning
- Role of patient preferences: limited
- Intentional vagueness: the panel decided to use the broad categories of neuromuscular disorders and craniofacial anomalies, rather than a comprehensive list of diseases and syndromes, to emphasize the need for individualized assessment
- Exclusions: none
- Policy level: recommendation

Statement 2. Advocating for PSG

The clinician should advocate for PSG prior to tonsillectomy for SDB in children without any of the comorbidities listed in statement 1 for whom the need for surgery is uncertain or when there is discordance between tonsillar size on physical examination and the reported severity of SDB.

Recommendation based on observational and case-control studies with a preponderance of benefit over harm.

Evidence Profile

- Aggregate evidence quality: grade C, observational and case-control studies
- Benefit: selection of appropriate candidates for tonsillectomy
- Harm: none
- Cost: time spent counseling the patient or family; financial implications to the family and insurance industry; time commitment for the study and follow-up
- Benefit-harm assessment: preponderance of benefit over harm
- Value judgments: based on expert consensus, there are circumstances in which PSG will improve diagnostic certainty and help inform surgical decisions
- Intentional vagueness: the panel decided to "advocate for" PSG rather than to "recommend" PSG in these circumstances to avoid setting a legal standard for care and to recognize the role for individualized decisions based on needs of the child and caregiver(s). Furthermore, the word *uncertain* is used in the statement to encompass a variety of circumstances regarding the need for tonsillectomy that include, but are not limited to, disagreement among clinicians or caregivers, questions about the severity of SDB or validity of the SDB diagnosis, or any other situation where the additional information provided by PSG would facilitate shared decisions
- Role of patient preferences: limited role in advocating; significant role in deciding whether or not to proceed with PSG
- Exclusions: none

Statement 3. Communication with Anesthesiologist

Clinicians should communicate PSG results to the anesthesiologist prior to the induction of anesthesia for tonsillectomy in a child with SDB.

Recommendation based on observational studies with a preponderance of benefit over harm.

Evidence Profile

- Aggregate evidence quality: grade C observational studies and grade D panel consensus
- Benefit: improve communication, provide information to the anesthesiologist that may alter perioperative management, reduce perioperative morbidity
- Harm: none
- Cost: none
- Benefit-harm assessment: preponderance of benefit over harm
- Value judgments: promoting a team approach to patient care will result in improved patient outcomes
- Intentional vagueness: none
- Role of patient preferences: none
- Exclusions: none

Statement 4. Inpatient Admission for Children with Obstructive Sleep Apnea (OSA) Documented in Results of PSG

Clinicians should admit children with OSA documented in results of PSG for inpatient, overnight monitoring after tonsillectomy, if they are under age 3 years or have severe OSA (apnea-hypopnea index of 10 or more obstructive events/hour, oxygen saturation nadir less than 80%, or both).

Recommendation based on observational studies with a preponderance of benefit over harm.

Evidence Profile

- Aggregate evidence quality: grade C, observational studies on age; diagnostic studies, guidelines, and panel consensus on what constitutes a severely abnormal PSG
- Benefit: PSG can help determine the appropriate setting for recovery after tonsillectomy that would allow prompt detection and management of respiratory complications among high-risk children
- Harm: unnecessary admission of children who do not have respiratory complications; occupying a hospital bed that might be better utilized; risk of iatrogenic injury (infection, parenteral narcotics causing respiratory depression, hyponatremia from hypotonic intravenous fluids, etc); reduced "family-centered care" during recovery process
- Cost: hospital admission; cost of monitoring
- Benefit-harm assessment: preponderance of benefit over harm
- Value judgments: despite the lack of consistent data on what constitutes severe OSA on PSG, the panel decided some criteria, based on consensus, should be provided to guide clinical decisions; perception by the panel that inpatient admission after tonsillectomy is underused for children with abnormal PSG and that obstacles exist in the health care system for precertifying inpatient admission, even when appropriate
- Intentional vagueness: none
- Role of patient preferences: limited
- Exclusions: none

Statement 5: Unattended PSG with Portable Monitoring (PM) Device

In children for whom PSG is indicated to assess SDB prior to tonsillectomy, clinicians should obtain laboratory-based PSG, when available.

Recommendation based on diagnostic studies with limitations and a preponderance of benefit over harm.

Evidence Profile

- Aggregate evidence quality: grade C, 1 small diagnostic study in children and extrapolation from diagnostic studies and guidelines for adults
- Benefit: avoid inaccurate results or misdiagnosis of OSA because of limitations in the precision and accuracy of currently used PM devices
- Harm: potential for delays in testing based on access to PSG and availability of child-friendly test facilities
- Cost: procedure-related direct cost
- Benefit-harm assessment: preponderance of benefit over harm
- Value judgments: the panel chose to emphasize accuracy of test results over convenience of testing. The term *when available* was used to acknowledge that although home studies have limitations, there may be circumstances when the caregivers express a strong preference for home-based testing or when access to laboratory-based PSG is limited by geography, scheduling conflicts, or insurance restrictions
- Intentional vagueness: none
- Role of patient preferences: some role for patient preference in deciding whether or not a PM device would be an acceptable alternative to PSG
- Exclusions: none

Definitions:

Guideline Definitions for Evidence-Based Statements

Statement	Definition	Implication
Strong recommendation	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B).* In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade B or C).* In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.

Option Statement	Definition	Implication
	An option means that either the quality of evidence that exists is suspect (grade D)* or that well-done studies (grade A, B, or C)* show little clear advantage to one approach vs another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
No recommendation	No recommendation means there is both a lack of pertinent evidence (grade D)* and an unclear balance between benefits and harms.	Clinicians should feel little constraint in their decision making and be alert to new published evidence that clarifies the balance of benefit vs harm; patient preference should have a substantial influencing role.

Evidence Quality for Grades of Evidence

Grade	Evidence Quality
A	Well-designed randomized controlled trials or diagnostic studies performed on a population similar to the guideline's target population
B	Randomized controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies
C	Observational studies (case control and cohort design)
D	Case reports, reasoning from first principles (bench research or animal studies)
X	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Sleep disordered breathing for which tonsillectomy is indicated

Guideline Category

Counseling

Diagnosis

Evaluation

Management

Risk Assessment

Clinical Specialty

Anesthesiology

Family Practice

Internal Medicine

Otolaryngology

Pediatrics

Sleep Medicine

Surgery

Intended Users

Advanced Practice Nurses

Physician Assistants

Physicians

Guideline Objective(s)

- To provide evidence-based recommendations for polysomnography (PSG) prior to tonsillectomy in children aged 2 to 18 years with sleep-disordered breathing as the primary indication for surgery
- To improve referral patterns for PSG among these patients
- To highlight the evidence for obtaining PSG in special populations or in children who have modifiable risk factors
- To define actions that could be taken by otolaryngologists to deliver quality care

Target Population

Children aged 2 to 18 years with sleep-disordered breathing who are candidates for tonsillectomy

Note: This guideline is *not intended* for the following populations:

Children younger than age 2 or older than age 18
Children who have already undergone tonsillectomy
Children having adenoidectomy alone
Children who are being considered for continuous positive airway pressure or other surgical therapy for sleep-disordered breathing

Interventions and Practices Considered

1. Polysomnography (PSG) (laboratory based)
2. Referral of specific patient groups for PSG
3. Advocating for PSG in specific patients
4. Communication of PSG results to anesthesiologist prior to tonsillectomy
5. Inpatient admission of patients following tonsillectomy

Major Outcomes Considered

- Prevalence of and risk for sleep-disordered breathing
- Severity of symptoms
- Accuracy of diagnosis
- Risk/incidence of perioperative complications (e.g., difficult airway, abnormal central respiratory drive, or abnormal cardiopulmonary

physiology)
- Risk/incidence of postoperative complications (e.g., respiratory compromise)
- Risk for long-lasting health consequences
- Treatment outcomes (e.g., changes in behavior, attention, quality of life, neurocognitive functioning, enuresis, parasomnias, or restless sleep)

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Several initial literature searches were performed through February 27, 2010, using MEDLINE, the National Guideline Clearinghouse (NGC) (www.guideline.gov), The Cochrane Library, Guidelines International Network (GIN), the National Research Register (NRR), ClinicalTrials.gov, the International Clinical Trials Registry Platform, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), and EMBASE. The initial search using "polysomnography" or "polysomnograph*" or "PSG" or "sleep apnea syndromes" or "apnea hypopnea index" or "respiratory disturbance index" or "AHI" or "RDI" or "sleep disorder*" or "sleep study*" or "sleep laboratory" in any field showed 5,686 potential articles:

1. Clinical practice guidelines were identified by an EMBASE, CINAHL, and MEDLINE and GIN search using *guideline* as a publication type or title word. The search identified 206 guidelines with a topic of polysomnography. After eliminating articles that did not have polysomnography as the primary focus, 49 guidelines were selected for the panel's discussion.
2. Systematic reviews were identified using a validated filter strategy that initially yielded 234 potential articles. The final data set included 34 systematic reviews or meta-analyses on polysomnography that were distributed to the panel members.
3. Randomized controlled trials were identified through the Cochrane Library (Cochrane Controlled Trials Register), MEDLINE, EMBASE, and CINAHL and totaled 24 trials.
4. Original research studies were identified by limiting the MEDLINE, CINAHL, and EMBASE search to articles on humans published in English. The resulting data set of 92 articles yielded 47 related to indications for polysomnography (PSG), 69 to advocating for PSG, 48 to postoperative monitoring, 6 to anesthesiology, and 2 to portable devices.

Results of all literature searches were distributed to guideline panel members, including electronic listings with abstracts (if available) of the searches for randomized trials, systematic reviews, and other studies. This material was supplemented, as needed, with targeted searches to address specific needs identified in writing the guideline through July 2010.

*High-risk populations include children with obesity, neuromuscular or craniofacial disorders, Down syndrome, mucopolysaccharidoses, or sickle cell disease.

Number of Source Documents

49 guidelines

34 systematic reviews or meta-analyses

24 randomized controlled trials

92 original research studies

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus (Committee)

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Evidence Quality for Grades of Evidence

Grade	Evidence Quality
A	Well-designed randomized controlled trials or diagnostic studies performed on a population similar to the guideline's target population
B	Randomized controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies
C	Observational studies (case control and cohort design)
D	Case reports, reasoning from first principles (bench research or animal studies)
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Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

The evidence-based approach to guideline development requires that the evidence supporting a policy be identified, appraised, and summarized and an explicit link between evidence and statements be defined. Evidence-based statements reflect both the quality of evidence and the balance of benefit and harm anticipated when the statement is followed. Definitions of evidence-based statements are listed in the "Rating Scheme for the Strength of the Evidence" and "Rating Scheme for the Strength of the Recommendations" fields.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

This guideline was developed using an explicit and transparent a priori protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm. The guideline development panel was chosen to represent the fields of pediatric anesthesiology, pediatric pulmonology, otolaryngology–head and neck surgery, pediatrics, and sleep medicine.

In a series of conference calls, the working group defined the scope and objectives of the proposed guideline. During the 10 months devoted to guideline development ending in September 2010, the group met twice, with interval electronic review and feedback on each guideline draft to ensure accuracy of content and consistency with standardized criteria for reporting clinical practice guidelines.

American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) staff used the Guideline Elements Model Conference on Guideline Standardization (GEM-COGS), the Guideline Implementability Appraisal and Extractor, to appraise adherence of the draft guideline to methodological standards, to improve clarity of recommendations, and to predict potential obstacles to implementation. Guideline panel members received summary appraisals in September 2010 and modified an advanced draft of the guideline.

Rating Scheme for the Strength of the Recommendations

Guideline Definitions for Evidence-Based Statements

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Recommendation	A recommendation means the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade B or C).* In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	An option means that either the quality of evidence that exists is suspect (grade D)* or that well-done studies (grade A, B, or C)* show little clear advantage to one approach vs another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
No recommendation	No recommendation means there is both a lack of pertinent evidence (grade D)* and an unclear balance between benefits and harms.	Clinicians should feel little constraint in their decision making and be alert to new published evidence that clarifies the balance of benefit vs harm; patient preference should have a substantial influencing role.

*See "Rating Scheme for the Strength of Evidence" for definition of evidence grades.

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The final draft practice guideline underwent extensive external peer review. Comments were compiled and reviewed by the group chairpersons, and a modified version of the guideline was distributed and approved by the development panel.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Recommendations contained in the practice guideline are based on the best available published data through July 2010. Where data were lacking, a combination of clinical experience and expert consensus was used.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of polysomnography for sleep-disordered breathing prior to tonsillectomy in children

For benefits of specific interventions considered in the guideline, see the "Major Recommendations" field.

Potential Harms

- Inpatient admission for monitoring following tonsillectomy may result in unnecessary admission of children who do not have respiratory complications; occupying a hospital bed that might be better utilized; risk of iatrogenic injury (infection, parenteral narcotics causing respiratory depression, hyponatremia from hypotonic intravenous fluids, etc.); reduced "family-centered care" during recovery process.
- Laboratory based polysomnography (PSG) versus a portable monitoring device for home testing has the potential for delays in testing based on access to PSG and availability of child-friendly test facilities.

Qualifying Statements

Qualifying Statements

- Guidelines are not intended to supersede professional judgment; rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less frequent variation in practice is expected for a "strong recommendation" than might be expected with a "recommendation." "Options" offer the most opportunity for practice variability. Clinicians should always act and decide in a way that they believe will best serve their patients' interests and needs, regardless of guideline recommendations. They must also operate within their scope of practice and according to their training. Guidelines represent the best judgment from a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.
- This clinical practice guideline is not intended as a sole source of guidance in prescribing polysomnography. Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. The guideline is not intended to replace clinical judgment or establish a protocol for all individuals who may benefit from polysomnography and may not provide the only approach to determining the appropriateness for polysomnography.
- As medical knowledge expands and technology advances, clinical indicators and guidelines are promoted as conditional and provisional proposals of what is recommended under specific conditions but are not absolute. Guidelines are not mandates; these do not and should not purport to be a legal standard of care. The responsible physician, in light of all the circumstances presented by the individual patient, must determine the appropriate treatment. Adherence to these guidelines will not ensure successful patient outcomes in every situation. The American Academy of Otolaryngology–Head and Neck Surgery emphasizes that these clinical guidelines should not be deemed to include all proper treatment decisions or methods of care, or to exclude other treatment decisions or methods of care reasonably directed to obtaining the same results.

Implementation of the Guideline

Description of Implementation Strategy

Implementation Considerations

The complete guideline is published as a supplement to Otolaryngology–Head and Neck Surgery to facilitate reference and distribution. The guideline was presented as a mini-seminar at the 2011 American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) Annual

Meeting & OTO Expo in San Francisco, CA. Existing brochures and publications by the AAO-HNS will be updated to reflect the guideline recommendations. A full-text version of the guideline is accessible to the public at the SAGE Journals Online Web site .

Implementation Tools

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Roland PS, Rosenfeld RM, Brooks LJ, Friedman NR, Jones J, Kim TW, Kuhar S, Mitchell RB, Seidman MD, Sheldon SH, Jones S, Robertson P. Clinical practice guideline: Polysomnography for sleep-disordered breathing prior to tonsillectomy in children. Otolaryngol Head Neck Surg. 2011 Jul;145(1 Suppl):S1-15. PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 Jul

Guideline Developer(s)

American Academy of Otolaryngology - Head and Neck Surgery Foundation - Medical Specialty Society

Source(s) of Funding

American Academy of Otolaryngology - Head and Neck Surgery Foundation

Guideline Committee

American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) Foundation Guideline Development Panel

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Financial Disclosure and Conflicts of Interest

The cost of developing this guideline, including travel expenses of all panel members, was covered in full by the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF). Potential conflicts of interest for all panel members in the past 5 years were compiled and distributed before the first conference call. After review and discussion of these disclosures, the panel concluded that individuals with potential conflicts could remain on the panel if they (1) reminded the panel of potential conflicts before any related discussion, (2) recused themselves from a related discussion if asked by the panel, and (3) agreed not to discuss any aspect of the guideline with industry before publication. Last, panelists were reminded that conflicts of interest extend beyond financial relationships and may include personal experiences, how a participant earns a living, and the participant's previously established "stake" in an issue.

Disclosures

Competing interests: Peter S. Roland: Advisory Board for MedE Corporation, Advisory Board for Entopica Therapeutics, and Advisory Board for Cochlear Corporation; consultant and speaker for Alcon Labs; consultant for Foresight Biotherapeutics; speaker for GlaxoSmithKline. Tae W. Kim: consultant for Cadence Pharmaceutical; advisory panel; and received funding for educational conference/course. Michael D. Seidman: director, Center for Integrative Medicine at Henry Ford Health System (HFHS); medical director, Wellness HFHS; founder, Body Language Vitamin Co; director, Product Development Visalus Sciences; minor shareholder, Arches Tinnitus Relief (<5%); author, *Save Your Hearing Now*; several patents; multiple National Institutes of Health and other sources of grant funding; scientific/medical advisor to major corporations (i.e., WebMD, BASF, NFL, MLB) and several startup companies.

Guideline Endorser(s)

Society of Otorhinolaryngology and Head and Neck Nurses - Medical Specialty Society

Guideline Status

This is the current release of the guideline.

A scheduled review process will occur at 5 years from publication or sooner if new compelling evidence warrants earlier consideration.

Guideline Availability

Electronic copies: Available from the SAGE Journals Online Web site .

Availability of Companion Documents

A podcast of the guideline is available for download from the SAGE Journals Online Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on October 5, 2011. The information was verified by the developer on November 21, 2011.

Copyright Statement

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